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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 328

Docket ID FEMA-2020-0018

RIN 1660-AB01

Prioritization and Allocation of Certain Scarce and Critical Health and Medical Resources for Domestic Use

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Temporary final rule; extension of effective date with modifications.

SUMMARY: In April, the Federal Emergency Management Agency (FEMA) issued a temporary final rule to allocate certain health and medical resources for domestic use, so that these resources may not be exported from the United States without explicit approval by FEMA. The rule covered five types of personal protective equipment (PPE), outlined below. While this rule remains in effect, and subject to certain exemptions stated below, no shipments of such designated materials may leave the United States without explicit approval by FEMA. Through this extension, FEMA modifies the types of PPE covered and extends the duration of the temporary final rule.

DATES: *Effective date:* This rule is effective from August 10, 2020 until December 31, 2020.

ADDRESSES: You may review the docket by searching for Docket ID FEMA-2020-0018, via the Federal eRulemaking Portal: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Daniel McMasters, Office of Policy and Program Analysis, 202-709-0661, *FEMA-DPA@fema.dhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On April 10, 2020, FEMA published a temporary final rule in the *Federal Register* allocating certain health and medical resources for domestic use, so that these resources may not be exported from the United States without explicit approval by FEMA.¹ The rule aids the response of the United States to the spread of Coronavirus Disease 2019 (COVID-19) by ensuring that certain health and medical resources are appropriately allocated for domestic use. On April 21, 2020, FEMA published a notification of exemptions to the rule.² With the continued goal of ensuring that such materials are appropriately allocated for domestic use, FEMA is extending the temporary final rule and modifying the list of covered materials to reflect current domestic supply needs. The temporary final rule will remain in effect until December 31, 2020, unless sooner modified or terminated by the Administrator.

A. The Current COVID-19 Pandemic

COVID-19 is a communicable disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), that was first identified as the cause of an outbreak of respiratory illness that began in Wuhan, Hubei Province, People's Republic of China. On January 30, 2020, the Director-General of the World Health Organization

¹ 85 FR 20195 (Apr. 10, 2020). *See also* 85 FR 22622 (Apr. 23, 2020) (correcting the date filed from "4-8-20" to "4-7-20").

² 85 FR 22021 (Apr. 21, 2020).

(WHO) declared that the outbreak of COVID-19 is a Public Health Emergency of International Concern under the International Health Regulations.³ The following day, the Secretary of Health and Human Services (HHS) declared COVID-19 a public health emergency under Section 319 of the Public Health Service (PHS) Act.⁴ On March 11, 2020, the WHO declared COVID-19 a pandemic. On March 13, 2020, the President issued a Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak under sections 201 and 301 of the National Emergencies Act, 50 U.S.C. 1601 *et seq.*, and consistent with section 1135 of the Social Security Act, 42 U.S.C. 1320b-5.⁵ On March 13, 2020, the President declared a nationwide emergency under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, authorizing FEMA to provide assistance for emergency protective measures to respond to the COVID-19 pandemic.⁶ FEMA subsequently issued 57 major disaster declarations in response to COVID-19 in every State, 5 territories, the Seminole Tribe of Florida, and the District of Columbia.⁷

Within the United States, widespread transmission of COVID-19 has occurred.

Widespread transmission of COVID-19 has resulted and will continue to result in large

³ Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV) (January 30, 2020), *available at* [https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)).

⁴ HHS, “Determination that a Public Health Emergency Exists,” *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx> (Jan. 31, 2020).

⁵ “Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak,” March 13, 2020, *available at* <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

⁶ COVID-19 Emergency Declaration *available at* <https://www.fema.gov/news-release/2020/03/13/covid-19-emergency-declaration> (accessed July 28, 2020).

⁷ See <https://www.fema.gov/disasters/> ([accessed July 28, 2020](#)).

numbers of people needing medical care at the same time. Public health and healthcare systems have become overwhelmed in some areas, with elevated rates of hospitalizations and deaths, as well as elevated demand for PPE, including the PPE covered by this rule.

B. Legal Authorities

FEMA is extending and modifying this temporary final rule as part of its response to the COVID-19 pandemic. The rule is issued pursuant to the following authorities, among others:

- The Defense Production Act of 1950, as amended (“DPA” or “the Act”), and specifically sections 101 and 704 of the Act, 50 U.S.C. 4511, 4554;
- Executive Order 13909, 85 FR 16227 (Mar. 23, 2020);
- Executive Order 13911, 85 FR 18403 (Apr. 1, 2020);
- Department of Homeland Security (DHS) Delegation Number 09052 Rev. 00.1, “Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency” (Apr. 1, 2020); and
- The Presidential Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (April 3, 2020).⁸

Under subsection 101(a) of the Act, 50 U.S.C. 4511(a), the President may (1) require that performance under contracts or orders (other than contracts of employment) which he deems necessary or appropriate to promote the national defense shall take priority over performance under any other contract or order, and, for the purpose of

⁸ See Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use for the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Administrator of the Federal Emergency Management Agency (Apr. 3, 2020), <https://www.whitehouse.gov/presidential-actions/memorandum-allocating-certain-scarce-threatened-health-medical-resources-domestic-use/> (last visited July 28, 2020).

assuring such priority, require acceptance and performance of such contracts or orders in preference to other contracts or orders by any person he finds to be capable of their performance. The President may also (2) allocate materials, services, and facilities in such manner, upon such conditions, and to such extent as he shall deem necessary or appropriate to promote the national defense. FEMA refers to these authorities as relating to “priority ratings” and “allocation,” respectively.

Under subsection 101(b) of the Act, 50 U.S.C. 4511(b), the President may not use the aforementioned authorities to control the general distribution of any material in the civilian market unless the President finds (1) that such material is a scarce and critical material essential to the national defense, and (2) that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship.

Under subsection 101(d) of the Act, 50 U.S.C. 4511(d), the head of each Federal agency to which the President delegates authority under section 101 of the Act (1) shall issue, and annually review and update whenever appropriate, final rules, in accordance with 5 U.S.C. 553, that establish standards and procedures by which the priorities and allocations authority under section 101 is used to promote the national defense, under both emergency and nonemergency conditions; and (2) as appropriate and to the extent practicable, consult with the heads of other Federal agencies to develop a consistent and unified Federal priorities and allocations system.

On March 18, 2020, the President signed Executive Order 13909, which (among other things) contained a finding that health and medical resources needed to respond to

the spread of COVID-19, including personal protective equipment and ventilators, meet the criteria specified in section 101(b) of the Act (50 U.S.C. 4511(b)).⁹

On March 27, 2020, the President signed Executive Order 13911, which (among other things) delegated to the Secretary of Homeland Security the President's authority under section 101 of the Act with respect to health and medical resources needed to respond to the spread of COVID-19 within the United States. The Executive Order provides that the Secretary of Homeland Security may use the authority under section 101 of the Act to determine, in consultation with the heads of other executive departments and agencies as appropriate, the proper nationwide priorities and allocation of health and medical resources, including by controlling the distribution of such materials (including applicable services) in the civilian market, for responding to the spread of COVID-19 within the United States.¹⁰ The Secretary of Homeland Security has delegated his authorities under Executive Order 13911 to FEMA. *See* DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020).

⁹ Executive Order 13909 also delegated to the Secretary of HHS authority under the DPA for the prioritization and allocation of health and medical resources to respond to the spread of COVID-19. Further, on March 23, 2020, the President signed Executive Order 13910, in which the President delegated to the Secretary of HHS the authority under section 102 of the Act to prevent hoarding and price gouging with respect to health and medical resources necessary to respond to the spread of COVID-19. On March 25, 2020, the Secretary of Health and Human Services designated under section 102 of the Act 15 categories of health and medical resources as scarce materials or materials the supply of which would be threatened by accumulation in excess of the reasonable demands of business, personal, or home consumption, or for the purpose of resale at prices in excess of prevailing market prices ("anti-hoarding designation"). *See* 85 FR 17592 (Mar. 30, 2020). The Secretary of HHS later modified and extended this designation. *See* 85 FR 45895 (July 30, 2020). The anti-hoarding designation relates to domestic hoarding and price-gouging activity, and is conceptually distinct from, and serves different purposes than, this rulemaking.

¹⁰ The Executive Order also delegated to the Secretary of Homeland Security the authority under section 102 of the Act to prevent hoarding and price gouging with respect to such resources, and requires that before exercising the authority under section 102 of the Act, the Secretary of Homeland Security shall consult with the Secretary of Health and Human Services.

Additionally, on April 3, 2020, the President signed a Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (the Memorandum). The Memorandum reaffirmed the delegations and findings contained in Executive Orders 13909 and 13911, including that health and medical resources needed to respond to the spread of COVID-19, including personal protective equipment (PPE), meet the criteria specified in section 101(b) of the Act, *i.e.*, that (1) such material is a scarce and critical material essential to the national defense, and (2) that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship. The Memorandum identified certain categories of PPE materials that the Secretary of HHS had previously designated as “scarce or threatened” for purposes of section 102 of the DPA, and further stated that to ensure that these materials remain in the United States for use in responding to the spread of COVID-19, it is the policy of the United States to prevent domestic brokers, distributors, and other intermediaries from diverting such PPE materials overseas.

In furtherance of such policy, the President directed the Secretary of Homeland Security, through the FEMA Administrator, and in consultation with the Secretary of HHS, to use any and all authority available under section 101 of the Act to allocate to domestic use, as appropriate, the five types of PPE identified in the Memorandum. On April 10, 2020, FEMA executed this direction by issuing the allocation order as a temporary final rule pursuant to the Memorandum, and with the authority delegated to the

Secretary of Homeland Security in EO 13911 and re-delegated to the FEMA Administrator in DHS Delegation 09052 Rev. 00.1.¹¹

Finally, on May 13, 2020, FEMA published an interim final rule to establish standards and procedures by which the priorities and allocations authority under section 101 is used to promote the national defense, under both emergency and nonemergency conditions.¹²

As the COVID-19 pandemic continues in the United States, the FEMA Administrator, in consultation with other agencies as appropriate, has determined that it must continue to allocate some materials contained in the April 10, 2020 temporary final rule for domestic use, but that it is no longer appropriate to continue the allocation of certain covered materials listed in the Memorandum due to changes in domestic supply and demand. In addition, FEMA has determined, consistent with the Memorandum and FEMA's authorities under section 101 of the DPA, that it is appropriate to designate an additional category of such materials. In short, FEMA has determined that the original temporary final rule must be extended, but the list of covered materials under such rule must be modified.

Consistent with the authority delegated to the Secretary of Homeland Security in EO 13911 and re-delegated to the FEMA Administrator in DHS Delegation 09052 Rev.

¹¹ See 85 FR 20195 (Apr. 10, 2020).

¹² See 85 FR 28500 (May 13, 2020) (codified at 44 CFR part 333). In that interim final rule, FEMA noted that although FEMA effectuated the April allocation order via a temporary rule that predated the interim final rule, FEMA retains authority to administer and enforce that allocation order according to its terms, and to issue future allocation orders consistent with the procedures announced in the interim final rule. See 85 FR at 28505. FEMA has opted to extend the April allocation, with modifications, consistent with the form of the April order.

00.1, FEMA now issues this temporary final rule to extend and modify the allocation order.

II. Provisions of the Temporary Final Rule

Following consultation with the appropriate Federal agencies; pursuant to the President's direction; and as an exercise of the Administrator's priority order, allocation, and regulatory authorities under the Act, the Administrator has determined that the April 10, 2020 temporary final rule ("covered materials") shall be extended temporarily, and that the list of scarce and critical materials identified in such temporary final rule shall be modified to reflect current domestic needs. The materials identified in this rule will continue to be allocated for domestic use, and may not be exported from the United States without explicit approval by FEMA. *See* 44 CFR 328.102(a).

The rule is necessary and appropriate to promote the national defense with respect to the covered materials because the domestic need for them exceeds the supply. Under this temporary final rule extension, before any shipments of such covered materials may leave the United States, U.S. Customs and Border Protection (CBP) will continue to detain the shipment temporarily, during which time FEMA will determine whether to return for domestic use, issue a rated order for, or allow the export of part or all of the shipment under section 101(a) of the Act, 50 U.S.C. 4511(a). FEMA will continue to make such a determination within a reasonable time of being notified of an intended shipment and will make all decisions consistent with promoting the national defense. *See* 44 CFR 328.102(b). FEMA will work to review and make determinations quickly and will endeavor to minimize disruptions to the supply chain.

In determining whether it is necessary or appropriate to promote the national defense to purchase covered materials, or allocate materials for domestic use, FEMA may continue to consult other agencies and will consider the totality of the circumstances, including the following factors: (1) the need to ensure that these items are appropriately allocated for domestic use; (2) minimization of disruption to the supply chain, both domestically and abroad; (3) the circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns; (4) the quantity and quality of the materials; (5) humanitarian considerations; and (6) international relations and diplomatic considerations.

This extension to the rule continues the eleven exemptions that the Administrator has determined to be necessary or appropriate to promote the national defense. *See* 44 CFR 328.102(c).

Specifically, the Administrator has determined that FEMA will not purchase covered materials from shipments made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020, so long as at least 80 percent of such manufacturer's domestic production of covered materials, on a per item basis, was distributed in the United States in the preceding 12 months. The Administrator decided that this exemption is necessary or appropriate to promote the national defense because it would limit the impact of this order on pre-existing commercial relationships, in recognition of the importance of these commercial relationships to the international supply chain, and for humanitarian reasons, in consideration of the global nature of the COVID-19 pandemic. If FEMA determines that a shipment of covered materials falls within this exemption, such materials may be

transferred out of the United States without further review by FEMA, provided that the Administrator may waive this exemption and fully review shipments of covered materials subject to this exemption for further action by FEMA, if the Administrator determines that doing so is necessary or appropriate to promote the national defense. FEMA may develop additional guidance regarding which exports are covered by this exemption and encourages manufacturers to contact FEMA with specific information regarding their status under this exemption.

On April 21, 2020, FEMA published notification of ten additional exemptions to the original temporary final rule.¹³ These exemptions will remain in effect for the new effective period of this rule, subject to the Administrator's discretion to waive, modify, or terminate such exemptions at any time in the future. The Administrator has determined that it continues to be necessary and appropriate in order to promote the national defense to exempt these categories of covered materials from the requirements of 44 CFR 328.102(a) and (b). The Administrator may establish, in his discretion, additional exemptions that he determines are necessary or appropriate to promote the national defense and will announce any such exemptions by notice in the *Federal Register*.

FEMA will continue to implement this rule with the cooperation and assistance of other U.S. Government agencies, including CBP, and will work with manufacturers, brokers, distributors, exporters, and shippers to ensure that the applicable requirements are carried out. Any covered materials intended for export may be detained by CBP while FEMA conducts its review of the shipment. FEMA will review the shipment and

¹³ 85 FR 22021 (Apr. 21, 2020).

provide notification as soon as possible regarding the disposition of the covered materials under this order, provided that any goods that have been detained by CBP and are subsequently made subject to a DPA-rated order will be consigned to FEMA pending further distribution or agency direction. FEMA may provide additional guidance regarding the application of any exemptions to this temporary final rule, as appropriate.

FEMA is modifying the original temporary final rule at section 328.103(a) to update the designation of covered materials under the rule. FEMA is reducing the list of covered materials to four types of PPE as these modifications reflect current domestic demand, as indicated by the number of open requests for such materials from State, local, Tribal, and territorial (SLTT) jurisdictions. Specifically—

- FEMA is continuing the designation of N95 Filtering Facepiece Respirators as covered materials, with one modification. In the original temporary final rule, FEMA designated “N95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates.” This temporary final rule modifies the existing language by adding the word, “surgical” to clarify the types of N95 Filtering Facepiece Respirators subject to this order. N95 respirators for medical use are still subject to high demand within the United States, and supply is not expected to catch up with demand until January 2021. As of August 4, 2020, FEMA had open requests for over 6 million N95 respirators from SLTT jurisdictions. Because this demand is specific to surgical N95 respirators and does not include industrial respirators, FEMA is clarifying that the list only covers surgical N95 respirators.

- FEMA is continuing the designation of PPE surgical masks as covered materials due to the continued inability of domestic supply to meet current demands. As of August 4, 2020, FEMA had open requests for over 28 million surgical masks from SLTT jurisdictions.

- FEMA is also continuing the designation of PPE gloves or surgical gloves as covered materials, with modification. FEMA is narrowing the scope of the materials covered to PPE nitrile gloves, specifically those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and other such nitrile gloves intended for the same purposes. Domestic supply for latex and vinyl examination and surgical gloves has largely caught up with demand, but there is still a significant shortage of nitrile gloves. As of August 4, 2020, FEMA had open requests for over 139 million nitrile gloves from SLTT jurisdictions.

- FEMA is adding designations for Level 3 and 4 Surgical Gowns and Surgical Isolation Gowns that meet all of the requirements in ANSI/AAMI PB70¹⁴ and ASTM F2407 – 06¹⁵ and are classified by Surgical Gown Barrier Performance based on AAMI PB70 to the covered materials list at this time as domestic supply is not meeting demand. As of August 4, 2020, FEMA had open requests for over 11 million of these gowns from SLTT jurisdictions.

- FEMA is eliminating two items from the covered materials list as there are currently no indications that supply is not meeting domestic demand to require these

¹⁴ ANSI/AAMI PB70 is the second edition of the standard for liquid barrier performance of protective apparel.

¹⁵ The American Society for Testing and Material (ASTM) F2407 is an umbrella document which describes testing for surgical gowns: tear resistance, seam strength, lint generation, evaporative resistance, and water vapor transmission.

items to continue to be subject to this order. FEMA is removing other filtering facepiece respirators as this category of respirator has seen a significant drop in the number of orders received from SLTT jurisdictions and the current supply is sufficient to fill demand from these jurisdictions. FEMA is also removing elastomeric, air-purifying respirators and appropriate particulate filters/cartridges from the list of covered materials as these items have seen low demand from SLTT jurisdictions and FEMA has been able to fill all orders that have been placed for these items in the past 45 days, as of July 16, 2020.

Note that this rule covers only those PPE items described above; it does not cover other forms of PPE not described in the rule, such as cloth-based masks.

Consistent with the DPA and the original temporary final rule, FEMA may continue to conduct such investigations and issue such requests for information as may be necessary for the enforcement of the Act, including this rule. *See* 44 CFR 328.104(a); *see also* section 705 of the Act, 50 U.S.C. 4555; Executive Order 13911, 85 FR 18403 (Apr. 1, 2020). FEMA may seek an injunction or other order whenever, in the Administrator's judgment, a person has engaged or is about to engage in any acts or practices which constitute or will constitute a violation of the Act or any rule or order issued thereunder. *See* 44 CFR 328.104(b); *see also* section 706 of the Act, 50 U.S.C. 4556. In addition to an injunction, failure to comply fully with this rule is a crime punishable by a fine of not more than \$10,000 or imprisonment for not more than one year, or both. *See* 44 CFR 328.104(c); *see also* section 103 of the Act, 50 U.S.C. 4513. In addition, pursuant to 18 U.S.C. 554, whoever fraudulently or knowingly exports or sends from the United States, or attempts to export or send from the United States, any merchandise, article, or object

contrary to any U.S. law or regulation, or receives, conceals, buys, sells, or in any manner facilitates the transportation, concealment, or sale of such merchandise, article, or object, prior to exportation, knowing the same to be intended for exportation contrary to any U.S. law or regulation, faces up to 10 years' imprisonment, a fine, or both, if convicted.

At any point in time, and to the extent consistent with United States policy, the FEMA Administrator may determine additional materials to be subject to this allocation order. Upon a determination under section 101(b) of the DPA that an additional material is a scarce and critical material essential for national defense, and that being allocated to domestic use under this allocation order is the only way to meet national defense requirements without significant disruption to the domestic markets, the Administrator will include these additional materials in this allocation order, and will provide notification of this decision through publication in the *Federal Register*.

III. Regulatory Procedure and Analyses

A. Temporary Final Rule with Immediate Effective Date

As explained in the original temporary final rule,¹⁶ agency rulemaking is generally governed by the agency rulemaking provisions of the Administrative Procedure Act (APA). *See* 5 U.S.C. 553. Such provisions generally require that, unless the rule falls within one of a number of enumerated exceptions, or unless another statute exempts the rulemaking from the requirements of the APA, FEMA must publish a notice of proposed rulemaking in the *Federal Register* that provides interested persons an opportunity to submit written data, views, or arguments, prior to finalization of regulatory requirements. Section 553(b)(B) authorizes a department or agency to dispense with the

¹⁶ 85 FR 20195 (Apr. 10, 2020).

prior notice and opportunity for public comment requirement when the agency, for “good cause,” finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

This rule is exempt from the APA under section 709(a) of the Act, 50 U.S.C. 4559(a). Instead, this rule is issued subject to the provisions of section 709(b). Pursuant to section 709(b)(2) of the Act, the Administrator has concluded, based on the facts related to the COVID-19 pandemic, which already have been summarized in this document, that, with respect to this temporary final rule, urgent and compelling circumstances make compliance with the notice and comment requirements of section 709(b)(1) of the Act, 50 U.S.C. 4559(b)(1), impracticable. If final regulations become necessary, an opportunity for public comment will be provided for not less than 30 days before such regulations become final, pursuant to section 709(b)(2)(C) of the Act, 50 U.S.C. 4559(b)(2)(C).

Furthermore, the same facts that warrant waiver under section 709(b)(2) of the Act would constitute good cause for FEMA to determine, under the APA, that notice and public comment thereon are impractical, unnecessary, or contrary to the public interest, and that the temporary final rule should become effective on August 10, 2020, the date on which the original temporary final rule would expire. The exigent need for this rule is related to the COVID-19 pandemic.

Although the Federal Government, along with State and local governments, have taken preventative and proactive measures to slow the spread of COVID-19, and to treat those affected, the ongoing spread of COVID-19 within the Nation’s communities is straining the Nation’s healthcare systems. It is imperative that health and medical

resources needed to respond to the spread of COVID-19, including the PPE affected by this rule, continue to be allocated for domestic use as appropriate. Given the evolving nature of this pandemic and the frequently changing supply of and demand for the health and medical resources needed to combat it, full public notice and comment proceedings are impracticable. As explained earlier in the preamble, the volume of requests for certain health and medical resources continues to outpace domestic supply in some cases, while the domestic supply of other health and medical resources is now sufficient to meet the requests of SLTT jurisdictions. In addition, the number of requests fluctuates widely from day-to-day as FEMA receives the requests, evaluates them, and satisfies them.

FEMA is continuously monitoring SLTT jurisdictions' demand for these scarce and critical health and medical resources. This immediate action is needed to continue to ensure that such resources are appropriately allocated for domestic use, and to tailor the scope of such allocation to current needs as of the prior TFR's scheduled end-date.

In short, given the national and international emergency caused by COVID-19 and the continuously evolving nature of the situation, FEMA finds that urgent and compelling circumstances have made it impracticable and contrary to the public health—and, by extension, the public interest—to delay these implementing regulations until a full public notice-and-comment process is completed. This temporary final rule modification and extension is needed to appropriately allocate scarce and critical materials for domestic use, based on current needs.

The measures described in this rule are being issued on a temporary basis. This temporary final rule will cease to be in effect on December 31, 2020, unless sooner modified or terminated by the Administrator.

B. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

The Office of Management and Budget has designated this temporary final rule as an economically significant regulatory action. Given that the temporary final rule is a significant regulatory action, FEMA proceeds under the emergency provision of Executive Order 12866, section 6(a)(3)(D) based on the need for immediate action, as described above, based on the need for immediate action to ensure these health and medical resources are appropriately allocated for domestic use.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that when an agency issues a proposed rule, or a final rule that the agency issues under 5 U.S.C. 553 after being required by that section or any other law to publish a general notice of proposed rulemaking, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the Federal Register. 5 U.S.C. 603, 604.

This is neither a proposed rule, nor a final rule that the agency has issued under 5 U.S.C. 553 of this title after being required by that section or any other law to publish a general notice of proposed rulemaking. This is a temporary final rule issued without a prior proposed rule, under the separate authority of the Defense Production Act of 1950. Accordingly, a regulatory flexibility analysis is not required.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), 2 U.S.C. 1532, requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately \$172 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. DHS has determined that this rule is not expected to result in expenditures by State, local, and Tribal governments, or by the private sector, of \$172 million or more in any one year.

This rule imposes no requirements on State, local, and Tribal governments and, therefore, cannot require them to expend any funds, let alone \$172 million. To the extent that this rule affects the private sector, it only prohibits conduct, namely certain exports. It does not require any private sector expenditures within the meaning of the Unfunded Mandates Act. Further, the rule is excluded from the Unfunded Mandates Act under 2 U.S.C. 1503(4) and (5).

E. National Environmental Policy Act (NEPA)

Under the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 4321 *et seq.*, an agency must prepare an environmental assessment or environmental impact statement for any rulemaking that significantly affects the quality of the human environment. FEMA has determined that this rulemaking does not significantly affect the quality of the human environment and consequently has not prepared an environmental assessment or environmental impact statement.

Rulemaking is a major Federal action subject to NEPA. Categorical exclusion A3 included in the list of exclusion categories at Department of Homeland Security Instruction Manual 023–01–001–01, Revision 01, Implementation of the National Environmental Policy Act, Appendix A, issued November 6, 2014, covers the promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, and advisory circulars if they meet certain criteria provided in A3(a-f). This temporary final rule meets Categorical Exclusion A3(a), “Those of a strictly administrative or procedural nature”.

F. Executive Order 13132: Federalism

This rule has been reviewed under Executive Order 13132, Federalism, 64 FR 43255 (August 4, 1999). That Executive Order imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. DHS has determined that this temporary final rule will not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of Government. Furthermore, there are no provisions in this rule that impose direct compliance costs on State and local governments. Accordingly, DHS believes that the rule does not warrant additional analysis under Executive Order 13132.

G. Congressional Review Act

Under the Congressional Review Act (CRA), 5 U.S.C. 801-808, before a rule can take effect, the Federal agency promulgating the rule must: submit to Congress and to the Government Accountability Office (GAO) a copy of the rule; a concise general statement relating to the rule, including whether it is a major rule; the proposed effective date of the rule; a copy of any cost-benefit analysis; descriptions of the agency's actions under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act; and any other information or statements required by relevant executive orders.

FEMA has sent this rule to the Congress and to GAO pursuant to the CRA. The Office of Information and Regulatory affairs has determined that this rule is a "major rule" within the meaning of the CRA. As this rule contains FEMA's finding for good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, there is not a required delay in the effective date. *See* 5 U.S.C. 808.

List of Subjects in 44 CFR Part 328

Administrative practice and procedure, Business and industry, Government contracts, Health or medical resource, Hoarding, Investigations, Materials, National defense, Scarce materials, Strategic and critical materials, Threatened materials.

Accordingly, for the reasons set forth in the preamble, and effective from August 10, 2020 until December 31, 2020, chapter I of title 44 of the Code of Federal Regulations is amended by revising part 328 to read as follows:

**PART 328—COVID-19 ALLOCATION ORDERS AND PRIORITY ORDER
REVIEW UNDER THE DEFENSE PRODUCTION ACT**

Sec.

- 328.101 Basis and purpose.
- 328.102 Requirements.
- 328.103 Designation of covered materials.
- 328.104 Investigations and injunctions; penalties.

AUTHORITY: Sections 101 *et seq.* of the Defense Production Act of 1950, 50 U.S.C. 4511, *et seq.*; Executive Order 13909, 85 FR 16227 (Mar. 23, 2020); Executive Order 13911, 85 FR 18403 (Apr. 1, 2020); DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020); Presidential Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (April 3, 2020).

§ 328.101 Basis and purpose.

(a) *Basis.* These rules are issued pursuant to section 101 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4511, and complementary authorities, including such authorities as are contained in subchapter III of chapter 55 of title 50, United States Code (50 U.S.C. 4554, 4555, 4556, and 4559), which have been delegated to FEMA.

(b) *Purpose.* The purpose of these rules is to aid the response of the United States to the spread of COVID-19 by ensuring that scarce or threatened health and medical resources are appropriately allocated for domestic use.

§ 328.102 Requirements.

(a) *Allocation Order and Requirement for the Administrator's Approval.* All shipments of covered materials, as designated in § 328.103, shall be allocated for domestic use, and may not be exported from the United States without explicit approval by FEMA.

(b) *Procedures.* U.S. Customs and Border Protection (CBP), in coordination with such other officials as may be appropriate, will notify FEMA of an intended export of covered materials. CBP must temporarily detain any shipment of such covered materials, pending the Administrator's determination whether to return for domestic use or issue a rated order for part or all of the shipment, pursuant to the Administrator's delegated authorities. The Administrator will make such a determination within a reasonable timeframe after notification of an intended export.

(c) *Administrator's Determination.* In making the determination described in paragraph (b) of this section, the Administrator may consult other agencies and will consider the totality of the circumstances, including the following factors:

- (1) The need to ensure that scarce or threatened items are appropriately allocated for domestic use;
- (2) Minimization of disruption to the supply chain, both domestically and abroad;
- (3) The circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns;
- (4) The quantity and quality of the materials;
- (5) Humanitarian considerations; and
- (6) International relations and diplomatic considerations.

(d) *Exemption.* (1) The Administrator has determined in the interest of promoting the national defense to generally allow the export of covered materials from shipments made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020, so long as at least 80 percent of such manufacturer's domestic production of such covered materials, on a per item basis, was distributed in the United States in the preceding 12 months. If FEMA determines that a shipment of covered materials falls within this exemption, such materials may be exported without further review by FEMA, provided that the Administrator may waive this exemption and fully review shipments of covered materials under paragraph (b) of this section, if the Administrator determines that doing so is necessary or appropriate to promote the national defense. FEMA will communicate to CBP regarding the application of this exemption to shipments identified by CBP.

(2) The Administrator may establish, in his discretion, additional exemptions that he determines necessary or appropriate to promote the national defense and will announce any such exemptions by notice in the *Federal Register*.

(e) *Exportations prohibited.* The exportation of covered materials other than in accordance with this section is prohibited.

§ 328.103 Designation of covered materials.

(a) The Administrator has designated the following materials as “covered materials” under this part:

(1) Surgical N95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates;

(2) PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials;

(3) PPE nitrile gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such nitrile gloves intended for the same purposes; and

(4) Level 3 and 4 Surgical Gowns and Surgical Isolation Gowns that meet all of the requirements in ANSI/AAMI PB70 and ASTM F2407-06 and are classified by Surgical Gown Barrier Performance based on AAMI PB70.

(b) Upon determination that additional items are scarce and necessary for national defense, and that consideration under this allocation order is the only way to meet national defense requirements without significant disruption to the domestic markets, the Administrator may designate additional materials as "covered materials" in the list provided above. The Administrator will publish notice of these additional "covered materials" in the *Federal Register*.

§ 328.104 Investigations and injunctions; penalties.

(a) To administer or enforce this subpart, the Administrator may exercise the authorities available under section 705 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4555, including the conduct of investigations, requests for information or testimony, and inspections of records or premises. Before such authorities

are utilized, the Administrator will determine the scope and purpose of the investigation, inspection, or inquiry, and be assured that no adequate and authoritative data are available from any Federal or other responsible agency.

(b) Whenever, in the judgment of the Administrator, any person has engaged or is about to engage in any acts or practices that constitute or will constitute a violation of any provision of this subpart, or order issued thereunder, the Administrator may exercise the authorities available under section 706 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4556, including applying for a preliminary, permanent, or temporary injunction, restraining order, or other order to enforce compliance with this subpart.

(c) Any person who willfully engages in violations of this part is subject to penalties available under section 103 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4513, or other available authority.

Pete Gaynor,

Administrator,

Federal Emergency Management Agency.

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